Supreme Court, U.S.
FILED
OCT 2 4 2003
OFFICE OF THE CLERK

No. 03-443

IN THE
Supreme Court of the United States

ALLERGAN, INC. and ALLERGAN SALES, INC.,

Petitioners,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
ALCON UNIVERSAL, LTD.,
and BAUSCH & LOMB INCORPORATED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT BAUSCH & LOMB INCORPORATED

EDWARD W. REMUS*
JONATHAN R. SICK
MCANDREWS HELD & MALLOY, LTD.
500 West Madison Street
Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Counsel for Respondent
Bausch & Lomb Incorporated

* *Counsel of Record*

183716

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether the owner of a method of use patent can bring a preemptive law suit under 35 U.S.C. § 271(e)(2), where the alleged infringer has filed an Abbreviated New Drug Application seeking approval from the Food and Drug Administration to market a generic drug for a use that is not covered by the patent?

CORPORATE DISCLOSURE STATEMENT

Respondent Bausch & Lomb Incorporated has no parent corporation nor are there any publicly held companies that own 10 percent or more of the stock of respondent Bausch & Lomb Incorporated.

TABLE OF CONTENTS

	Page
Question Presented	i
Corporate Disclosure Statement	ii
Table of Contents	iii
Table of Cited Authorities	v
Opinions Below	1
Statement of the Case	1
A. The New Drug Application	2
B. Petitioner's Method of Use Patents and the Patent Listing Procedure	4
C. The Abbreviated New Drug Application	5
D. Petitioner's Infringement Claims	7
Reasons for Denying the Petition	9
I. There Are No Conflicting Decisions Below Nor Exceptional Questions Of Law Which Would Warrant The Attention Of This Court	11
A. The Issue Raised By Petitioner Has Been Put To Rest By The Federal Circuit	11

Contents

Page

B. Research-Based Drug Patent Owners Are Not Left Without Incentives To Research and Develop New Uses For Existing Drugs 12

II. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(e)(2) Comports With Legislative History And Public Policy 14

Conclusion 21

TABLE OF CITED AUTHORITIES

Page

Cases:

Alcon Labs., Inc. v. Allergan, Inc.,
256 F. Supp. 2d 1080 (C.D. Cal. 2003) 19, 20

Allergan, Inc. v. Alcon Labs., Inc.,
200 F. Supp. 2d 1219 (C.D. Cal. 2002) 1

Allergan, Inc. v. Alcon Labs., Inc.,
324 F.3d 1322 (Fed. Cir. 2003) 1, 11, 16, 17

Bonito Boats Inc. v. Thunder Craft Boats, Inc.,
489 U.S. 141 (1989) 3

Eli Lilly & Co. v. Medtronic, Inc.,
496 U.S. 661 (1990). 5, 15

Glaxo, Inc. v. Novopharm, Ltd.,
110 F.3d 1562 (Fed. Cir. 1997) 2

Graham v. John Deere Co.,
383 U.S. 1 (1966) 20

Oklahoma v. New Mexico,
501 U.S. 221 (1991) 15

Warner-Lambert Co. v. Apotex Corp.,
316 F.3d 1348 (Fed. Cir. 2003) ..... *passim*

Cited Authorities

Page

Statutes:

21 U.S.C. § 331 7

21 U.S.C. § 332 7

21 U.S.C. § 333 7

21 U.S.C. § 334 7

21 U.S.C. § 352 7

21 U.S.C. § 355 4

21 U.S.C. § 355(b)(1) 4

21 U.S.C. § 355(j) 7

21 U.S.C. § 355(j)(2)(A)(i) 5

21 U.S.C. § 355(j)(2)(A)(ii)(I) 5

21 U.S.C. § 355(j)(2)(A)(iii) 5

21 U.S.C. § 355(j)(2)(A)(iv) 5

21 U.S.C. § 355(j)(2)(A)(v) 6

21 U.S.C. § 355(j)(2)(A)(vii) 6

Cited Authorities

	Page
21 U.S.C. § 355(j)(5)(B)(iii)	20
21 U.S.C. § 355(j)(5)(B)(iii)(I)	7
21 U.S.C. § 355(j)(5)(D)(ii)	5
35 U.S.C. § 271(b)	12
35 U.S.C. § 271(e)(2)	*passim*
Regulations:	
21 C.F.R. § 314.53(b)	4
21 C.F.R. § 314.53(e)	4
Other Authorities:	
68 Fed. Reg. 36,677	19
68 Fed. Reg. 36,681	18
68 Fed. Reg. 36,704	18

OPINIONS BELOW

The decision of the district court granting respondent Alcon's motion for summary judgment was entered on May 8, 2002 and is reported at *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F. Supp. 2d 1219 (C.D. Cal. 2002). The decision of the district court granting respondent Bausch & Lomb's ("B&L") motion for summary judgment was entered on June 4, 2002 and is unreported. The opinion of the Federal Circuit affirming the grant of summary judgment in favor of respondents Alcon and B&L was entered on March 28, 2003, and is reported at *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed. Cir. 2003). The order of the Federal Circuit denying petitioner Allergan's request for rehearing *en banc* was entered on May 22, 2003 and is unreported.

STATEMENT OF THE CASE

The question "of exceptional importance" which petitioner Allergan seeks to have the Court review is not the subject of conflicting decisions by the Federal Circuit below. Nor is it a question that was decided by a "close" split of the full Federal Circuit sitting *en banc*. Rather, the issue was previously decided by a unanimous three-judge panel of the Federal Circuit in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), a decision for which further review was never sought. When the same issue arose in this case, a second three-judge panel of the Federal Circuit followed the holding of the *Warner-Lambert* panel, albeit reluctantly. When Allergan petitioned to have the question reheard by the full Federal Circuit sitting *en banc*, the Federal Circuit summarily declined.

\ At issue is whether the owner of a patent which covers a particular method of using a drug can bring a preemptive patent infringement law suit under 35 U.S.C. § 271(e)(2) against a generic drug manufacturer that files an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), where the ANDA seeks approval to market the drug for a method of use ***that is not covered by the patent***. Recognizing that to allow such a suit would lead to an absurd scenario in which a generic drug company would be precluded from selling to the consumer a public domain drug for a public domain use of that drug, the Federal Circuit quite understandably answered the question in the negative. As a result, research-based drug companies such as petitioner cannot seek ***preemptive*** relief under this narrow set of circumstances. Of course, all of the traditional remedies for patent infringement are still available to these patent holders, which provide more than enough incentive for them to research new uses of existing drugs.

A. The New Drug Application

Congress enacted the Hatch-Waxman Act in 1984 "to benefit makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). One of the benefits to research-based pharmaceutical companies was the implementation of the New Drug Application ("NDA") system under which a period of marketing exclusivity would be granted to companies which conducted clinical studies to establish the safety and efficacy of a drug product – even if the drug product was in the public domain. Petitioner took advantage of this system to obtain a period of marketing exclusivity for a drug containing "brimonidine" as its active ingredient.

The chemical "brimonidine" was originally patented in 1975 by Pfizer as a drug useful for treating hypertension. The Pfizer patent expired in 1992. Brimonidine is, therefore, in the public domain. *Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) ("It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property."). As early as 1986, researchers published findings showing that, when applied topically to ocular tissue, brimonidine was effective in reducing intraocular pressure ("IOP") in rabbits, cats and monkeys. By 1995, brimonidine had been used to lower IOP in humans, and specifically for the treatment of "glaucomatous hypertension" in humans. Thus, the use of brimonidine to lower IOP in mammals, including humans having glaucoma and ocular hypertension, is in the public domain.

In 1995, petitioner filed an NDA with the FDA for approval to market an ophthalmic drug product containing brimonidine as its active ingredient. The FDA does not grant approvals to market a drug for any purpose; rather, the applicant must specify the use (or uses) for the drug and submit clinical data which demonstrates that the drug is effective for that use. Petitioner's NDA sought approval for one use of the brimonidine drug and one use only – "lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension." Petitioner submitted clinical and other data to the FDA establishing the safety and efficacy of the drug only for this use. In September 1996, the FDA approved petitioner's NDA for the *sole use* of lowering IOP.

The approval of petitioner's NDA entitled it to a five and a half year period of marketing exclusivity, even though

the use of brimonidine to lower IOP in patients with open-angle glaucoma or ocular hypertension was in the public domain. Petitioner's period of FDA-granted exclusivity expired on March 6, 2002.

B. Petitioner's Method of Use Patents and the Patent Listing Procedure

During this period of exclusivity, petitioner filed for and was granted two patents which are directed to a method of using brimonidine in mammals to achieve the effect of "neuroprotection." Petitioner uses the term "neuroprotection" to describe the direct treatment of the optic nerve to prevent glaucoma, as distinct from treatments which lower IOP. Thus, the claims of these patents (referred to hereinafter as "the neuroprotection patents") do not cover the use of brimonidine to lower IOP.

Under 21 U.S.C. § 355 (the section of the Food, Drug and Cosmetic Act pertaining to NDAs), the owner of an approved NDA is required to provide to the FDA the identity of patents which cover the approved drug product. According to the FDA regulations implementing 21 U.S.C. § 355, "[f]or patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53(b).[1] The submitted patents are published by the FDA in the "Orange Book." *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e).

---

1. The FDA recently amended its regulations to make it even more clear that only patents which claim a method of use ***for which the drug has been approved*** should be listed. *See* discussion *infra* Part II.

After the neuroprotection patents issued, petitioner submitted them for listing with the FDA, despite the fact that they do not claim the use of brimonidine to lower IOP, the only use set forth in the NDA. Since the FDA does not check the substance of its listings, but merely acts in a clerical, ministerial capacity, the FDA listed these patents in its "Orange Book."

C. The Abbreviated New Drug Application

Another purpose of the Hatch-Waxman Act was "to enable new drugs to be marketed more cheaply and quickly." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). To this end, near the end of the period of exclusivity granted to the holder of an approved NDA, a competitor may file an ANDA to seek approval to market a generic version of the drug once the period of exclusivity expires. *See* 21 U.S.C. § 355(j)(5)(D)(ii). In October 2001, respondent B&L submitted an ANDA to the FDA seeking approval to market a generic version of petitioner's brimonidine product.

Unlike an NDA, an ANDA applicant is not required to submit human clinical studies to show that the drug is safe and effective for various uses for which the manufacturer seeks approval. An ANDA simply contains information which supports bioequivalence to the brand-name drug product, usually because it contains the same ingredients. *See* 21 U.S.C. §§ 355(j)(2)(A)(ii)(I), 355(j)(2)(A)(iii), 355(j)(2)(A)(iv). Since an ANDA does not contain human clinical data, by law, a generic drug cannot be approved for any use beyond the uses approved by the FDA in the brand-name's NDA. 21 U.S.C. § 355(j)(2)(A)(i).

Moreover, the labeling for the generic drug is required to be the same as the labeling for the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(v). As a result, respondent B&L sought approval from the FDA to market and label its generic brimonidine product for one use and one use only – the public domain use of "lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension." Since the neuroprotective use claimed in petitioner's patents is different from the labeled use of lowering IOP, the neuroprotective use is referred to as an "off-label" use.

As part of its application, an ANDA applicant is required to submit a certification, with respect to each listed and unexpired patent "which claims a use for such listed drug for which the applicant is seeking approval . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . ." 21 U.S.C. § 355(j)(2)(A)(vii). In respondent's view, there was no need to submit a certification with respect to petitioner's neuroprotection patents because neither patent claims the use for which respondent was seeking approval: the lowering of IOP. Nevertheless, out of an abundance of caution, and because petitioner had listed the neuroprotection patents with the FDA (improperly in respondent's view) and the FDA had published the patents in the Orange Book, respondent B&L filed a certification that those patents would not be infringed.

After respondent B&L notified the petitioner of its ANDA (such notification is required when an ANDA applicant files a certification that a patent will not be infringed), petitioner shortly thereafter filed suit against respondent B&L for patent infringement under 35 U.S.C. § 271(e)(2) (petitioner simultaneously filed suit against

respondent Alcon). By filing this suit, petitioner automatically triggered a provision of 21 U.S.C. § 355(j) which prevents the FDA from approving a generic product for 2½ years unless a judgment of noninfringement or invalidity is rendered prior to the expiration of that time. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

D. Petitioner's Infringement Claims

Title 35 of U.S.C. § 271(e)(2) provides that "[i]t shall be an act of infringement to submit –

> . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

Respondent B&L, as a manufacturer of brimonidine, will not itself use the drug for the alleged neuroprotection. B&L is also precluded from promoting brimonidine for neuroprotection. Under FDA law, drug manufacturers and sellers – including B&L – cannot legally promote any use of a drug except the one approved by the FDA. *See* 21 U.S.C. §§ 331, 332, 333, 334, 352.

Nevertheless, petitioner Allergan alleged in the district court that if respondent B&L were to obtain approval to bring its generic brimonidine drug product to the market, B&L would then ***actively induce*** doctors and patients to use that drug for the neuroprotective uses covered by petitioner's

patents. Thus, argued petitioner, B&L's filing of an ANDA for approval to market a drug containing brimonidine was an act of infringement under 35 U.S.C. § 271(e)(2).

Whether or not respondent B&L would seek to actively induce the infringement of petitioner's patents upon obtaining approval of its ANDA (which it would not do) is irrelevant to the issue that petitioner would have the Court review (whether section 271(e)(2) can ever be invoked with an off-label use patent). Nonetheless, in what is apparently a desperate effort to influence the Court by painting respondent B&L in a poor light, petitioner makes a number of factual misstatements that respondent B&L is compelled to correct.

In particular, B&L is not "fully aware . . . that . . . the vast majority of glaucoma patients are candidates for neuroprotective treatment, and that respondents' generic versions of brimonidine can and will be used for the unapproved neuroprotective use claimed in petitioner's patent." Petition at 8. Petitioner failed to produce any credible evidence that doctors are actually prescribing brimonidine for the so-called effect of neuroprotection, and B&L is certainly not aware of any such activity by doctors. The best that can be said is that research into the neuroprotective properties of brimonidine is ongoing, but no concrete evidence supports the conclusion that brimonidine achieves this effect in humans. Therefore, B&L does not "know" that its brimonidine product will be used, contrary to its labeling, for neuroprotection.

Furthermore, respondent B&L has not, as petitioner would have the Court believe, taken any steps to encourage the use of brimonidine for neuroprotection. Petitioner's "evidence" is that B&L sponsors a research website upon

which one can find an abstract about neuroprotection. What petitioner omits is that the website is owned by a University and operated completely independent of respondent B&L, and indeed the site contains a conspicuous statement that B&L is ***not involved*** in and does not make any representations about the content of the website. Furthermore, the abstract in question which can be found by searching the database on the site ***was authored by the petitioner.*** It strains credulity to suggest that B&L is actively inducing doctors to make neuroprotective use of brimonidine in humans rather than the use to lower IOP, because B&L simply provides a monetary donation to a University that independently monitors the published literature, stores it on a web-site database with thousands of already-published ophthalmic articles, such that, if the database is searched by a person looking for "brimonidine," the person can find among other articles an article written an published by petitioner Allergan, which would be found elsewhere by searching the web anyway.

REASONS FOR DENYING THE PETITION

Petitioner has presented no compelling reason for the Court to grant its petition. First, there is no conflict among the federal courts which requires resolution by this Court, and the issue raised by petitioner is not such an important question of federal law as to warrant review by this Court. In particular:

- The issue was decided by a unanimous three-judge panel of the Federal Circuit, and when invited to consider the case *en banc*, the Federal Circuit declined.

- Notwithstanding petitioner's farfetched arguments to the contrary, drug patent holders have not been stripped of all incentives as a result of the Federal Circuit's decision. While research-based drug companies such as petitioner may be precluded from bringing a preemptory action to automatically prevent entry into the market for all uses (including public domain uses) of a particular drug, there is no question that, on the very day that a generic drug enters the market, those companies can bring suit for induced infringement and move for a temporary restraining order and a preliminary injunction against the off-label uses – assuming they have the appropriate strong evidence of inducement to support this extreme relief.

Second, the petition should be denied because the Federal Circuit's interpretation of the statute is the correct one. The plain language of the statute, coupled with the statutory framework of the Hatch-Waxman Act, its legislative history, and public policy concerns, compel the conclusion reached by the Federal Circuit that section 271(e)(2) provides no cause of action for infringement of method patents that do not claim the method for which an ANDA applicant is seeking approval.

I. There Are No Conflicting Decisions Below Nor Exceptional Questions Of Law Which Would Warrant The Attention Of This Court

A. The Issue Raised By Petitioner Has Been Put To Rest By The Federal Circuit

Petitioner makes much out of the fact that the concurring opinions from the *Allergan* decision below criticized the Federal Circuit's decision in the *Warner-Lambert* case. The fact is, however, that the panel below followed the *Warner-Lambert* decision and thus created no conflict in the precedent. Not satisfied with this outcome, petitioner put the issue squarely before the entire Federal Circuit by petitioning for rehearing *en banc*. The Federal Circuit declined such a rehearing summarily in an unreported decision. This puts to rest any question over whether there is a split in Federal Circuit authority on this issue. Furthermore, the decision to decline rehearing *en banc* suggests that this issue was not considered to be of exceptional importance to the members of the Federal Circuit.

It is also worth noting that when this issue was decided against a major research-based pharmaceutical company in the *Warner-Lambert* case, that company did not elect to petition for rehearing *en banc*, or to petition for a writ of certiorari as Allergan has done here. One would have expected such activity by this party if the *Warner-Lambert* decision would truly lead to the dire consequences that petitioner Allergan predicts.

B. Research-Based Drug Patent Owners Are Not Left Without Incentives To Research and Develop New Uses For Existing Drugs

Petitioner over-inflates the importance of the issue raised by its petition by arguing that the Federal Circuit's decision "essentially destroys patent protection" and "severely undermines financial incentives for developing important new uses for existing drugs." Petition at 13-14. To the contrary, there is nothing in the Hatch-Waxman Act that would preclude companies like petitioner from bringing a traditional infringement suit against generic companies – once those companies have entered the market.

In other words, as long as a company such as petitioner Allergan has a good faith basis to support its allegations, it can bring a suit for induced infringement under 35 U.S.C. § 271(b) on the very same day that the generic company launches its drug product. If the patentee is concerned about immediate, irreparable harm, and it has the strong evidence to support such extraordinary relief, it can move for a temporary restraining order or a preliminary injunction. The only "remedy" that the Federal Circuit has deprived patentees such as petitioner of is the right to bring a ***preemptory*** lawsuit against a generic company, and to obtain an automatic 30-month stay of the ANDA process for ***all*** uses, with a patent directed to a use (1) that is not approved by the FDA, and (2) for which the generic company is not seeking approval.

Petitioner argues that it needs this preemptive relief as an incentive to innovate because the traditional patent infringement remedies are unsatisfactory. Petition at 16-17 ("remedy of a preliminary injunction is illusory at best" and

"nor does a damages remedy provide the assurance of recovery necessary to foster innovative new uses of drugs"). But the same complaints could be made by any patent holder, not just those in the pharmaceutical industry. The reality is that the threat of an infringement action ***will*** deter a generic drug manufacturer from taking actions that would render it liable for inducement to infringe. The cost to a generic company of constructing manufacturing facilities and gearing up to distribute a new product is far from insignificant. The threat of losing the value of this investment through an injunction, or the threat of being put out of business by incurring liability for a research-based drug company's lost profits, is more than enough encouragement to avoid infringing activities.

The heart of petitioner's concern seems to be not what generic companies will or will not do once their products are on the market, but how doctors will prescribe those drugs once they get their hands on them, since doctors are not bound by the labeling on the product. This repeated theme throughout Allergan's petition, while perhaps interesting, only serves to emphasize how misplaced its arguments are. The makers of generic drugs such as respondent B&L ultimately have no control over how doctors prescribe drugs, including whether they will choose to prescribe a given drug for an off-label use. Taking petitioner's arguments to their natural conclusion, the incentives of research-based drug companies will not be restored until generic companies are held to a strict liability standard under which, no matter how pure the motives of the generic companies, they are responsible for all infringing off-label uses of their drugs by doctors. Such a rigid requirement would certainly unduly suppress the flow of generic drugs to the consumer, and thus contravene the purposes of the Hatch-Waxman Act.

If petitioner is unhappy that doctors have the discretion to prescribe medications for off-label uses, perhaps it should look to address those concerns in a forum other than the courts.

The Federal Circuit's interpretation of section 271(e)(2) has not destroyed the incentives that would drive research-based drug companies to develop new uses of existing drugs. Petitioner is complaining because it lost a remedy that Congress never intended it to have, one that would artificially extend its patent monopoly to cover public domain drugs and public domain methods of using those drugs. There is no question, however, that petitioner, and research-based drug patent holders like it, can avail themselves of traditional patent infringement remedies if they have a good faith basis to do so.

II. The Federal Circuit's Interpretation Of 35 U.S.C. § 271(e)(2) Comports With Legislative History And Public Policy

The drug involved in this litigation, brimonidine, is in the public domain. Its use to lower intraocular pressure in glaucoma patients is also in the public domain. These facts are undisputed. Petitioner is essentially demanding, as "compensation" for its neuroprotection patents (which use is not approved by the FDA), the right to preclude (or at least to significantly delay entry into the market) a generic company's use of a public domain drug and method. As the Federal Circuit recognized in *Warner-Lambert*, any statutory interpretation that would allow this is inconsistent with "the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." 316 F.3d at 1359.

Warner-Lambert began its analysis by examining the plain language of section 271(e)(2), repeated in pertinent part here:

> It shall be an act of infringement to submit . . . [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Focusing on the fact that Congress chose to use the word "the" before "use", instead of "a" or "any", the panel concluded that "the statutory language 'the use' is most reasonably interpreted to mean 'the use listed in the ANDA.' Congress could have been expected to use quite different language if it wanted to reach the opposite result." 316 F.3d at 1356.

The *Warner-Lambert* analysis did not end with the plain language, however. It is well established that when confronting ambiguous language in a statute, resort to the legislative history and policies underlying the statute are appropriate. *See, e.g., Oklahoma v. New Mexico*, 501 U.S. 221, 235 n.5 (1991) ("we repeatedly have looked to legislative history and other extrinsic material when required to interpret a statute which is ambiguous"); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). *Warner-Lambert* went on to analyze portions of the legislative history of the Hatch-Waxman Act, [illegible]ding statements in the House Reports that demonstrated Congressional intent to limit the remedies

of section 271(e)(2) to patents that claim a method of use for which the ANDA applicant is seeking approval. 316 F.3d at 1359-60 ("Congress made it clear that the ANDA applicant need not certify with respect to every 'use' patent . . . Rather, the applicant needs only to certify with respect to use patents that claim an indication *for which the applicant is seeking approval to market the drug*."). The Federal Circuit also examined other parts of the statutory framework arising from the Hatch-Waxman Act, and found that language to be consistent with its interpretation of section 271(e)(2). *Id.* at 1360-62.

Finally, *Warner-Lambert* considered public policy concerns and found those to favor its interpretation of section 271(e)(2). In particular, the panel found that the appellant's interpretation of section 271(e)(2), which is the same as that advocated by both petitioner and the concurring *Allergan* opinions below ("the *Allergan* concurrences"), would effectively bar generic drug manufacturers from bringing public domain products and their public domain uses to the market, a result in direct conflict with the expressed Congressional purpose of making available "more low cost generic drugs." *See id.* at 1359. *Warner-Lambert* thus premised its interpretation of section 271(e)(2) on a reasoned analysis of all the applicable authorities, including the plain language of the statute, other statutory language within the Hatch-Waxman Act framework, legislative history, and public policy concerns.[2]

---

2. Indeed, as noted above, the *Warner-Lambert* decision was so well-reasoned that none of the parties (which included a major pharmaceutical company) saw fit to file a petition for panel rehearing, a petition for rehearing *en banc*, or even a petition for writ of *certiorari*.

Drawing support from the *Allergan* concurrences, petitioner would interpret section 271(e)(2) in a manner directly contrary to the *Warner-Lambert* decision and yet, dismiss with little consideration much of the legislative history and policy concerns raised by *Warner-Lambert*. This is not an oversight; rather, both petitioner and the *Allergan* concurrences find the language of section 271(e)(2) so plain and unambiguous as to require no resort to public policy or legislative history. Respondent submits that this deliberate decision to pass over the legislative history and public policy issues, in the face of the *Warner-Lambert* panel's contradictory interpretation of the statue, undermines petitioner's position and reveals the weakness of the *Allergan* concurrences.

The language of section 271(e)(2) is, at best, ambiguous. After all, what better case of ambiguity could there be than two different three-judge panels of the Federal Circuit reaching diametrically-opposed conclusions as to the "plain meaning" of the same statutory language? Despite their knowledge of the contrary *Warner-Lambert* decision, petitioner and the *Allergan* concurrences would rest on their conclusion that the language of section 271(e)(2) is plain on its face and thus refuse to fully address contrary legislative history and policy concerns. The prevailing interpretation of the Federal Circuit, which is backed by a full analysis of the legislative history and policy concerns surrounding the Hatch-Waxman Act, is the correct one.

The Federal Circuit's interpretation of section 271(e)(2) finds support in recent amendments to FDA regulations. In the June 18, 2003 Federal Register, the FDA published

the following amendment to its patent submission and listing requirements for NDAs:

> For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use ~~of a~~ ***that are described in the*** pending or approved application. ***The applicant shall separately identify each pending or approved method of use and related patent claim.***

68 Fed. Reg. 36,704 (2003)[3] (new text shown in bold and italics, deleted text with strikethrough). The FDA explained its rule amendment as follows:

> All of the benefits afforded NDA holders under the Hatch-Waxman Amendments, such as the 30-month stay, derive from obtaining our approval of a particular drug product. Accordingly, only method-of-use patents that claim a use of the drug product in the pending or approved application must be submitted. Method-of-use patents for uses that the NDA holder "has not chosen to make available to the public" must not be submitted for listing.

68 Fed. Reg. 36,681 (citation omitted). This clarified rule and explanation make it abundantly clear that patents covering off-label uses should not be submitted to the FDA for listing in the Orange Book, and it follows that such patents cannot serve as the basis of an infringement action under section 271(e)(2). Notably, the FDA's rule amendments were,

3. Available at *http://www.fda.gov/OHRMS/DOCKETS/98fr/061803a.pdf.*

at least in part, a response to the FTC study entitled "Generic Drug Entry Prior to Patent Expiration" which petitioner cites to support its position that the Federal Circuit's interpretation is wrong. *See* 68 Fed. Reg. 36,677; Petition at 20.

Another policy concern supporting the Federal Circuit's rejection of petitioner's interpretation of section 271(e)(2) is that it would lead to abusive practices by research-based drug companies:

> If Warner-Lambert's interpretation were correct, for example, an NDA holder would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA. It would then be able to use § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market.

Warner-Lambert, 316 F.3d at 1359.

Petitioner made these concerns a reality. In October 2002, while petitioner's Federal Circuit appeal was pending, petitioner obtained yet another, new, neuroprotection patent which it subsequently listed in the FDA's "Orange Book." *See Alcon Labs., Inc. v. Allergan, Inc.*, 256 F. Supp. 2d 1080, 1083 (C.D. Cal. 2003). Disturbingly close to the *Warner-Lambert* panel's prediction, petitioner's "new" patent is a slightly narrower (in claim scope) version of its other two patents which cover the use of brimonidine for neuroprotection. Once respondent B&L had filed the requisite

certification that it would not infringe this newly-listed patent after its ANDA were approved, petitioner filed yet another suit against B&L (and also against respondent Alcon) under section 271(e)(2) (this time in ***Delaware*** instead of the forum of the original case, California). *Id.*

Of course, petitioner's act of simply filing suit triggered another automatic 30-month stay of the ANDA approval process. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Respondents successfully moved to have the case transferred back to California, and the district court has now entered judgment against petitioner on this new patent, based on reasoning similar to that in its original opinion as well as on the *Warner-Lambert* decision. *See Alcon*, 256 F. Supp. 2d 1080. Petitioner Allergan was "gaming" the system in exactly the manner that *Warner-Lambert* feared. If the Federal Circuit's *Warner-Lambert* interpretation is reversed, these types of abusive practices will continue.

In the end, there are strong legislative history and policy concerns supporting the Federal Circuit's interpretation of section 271(e)(2). The Federal Circuit's decision put to rest the abusive practices of companies such as petitioner which, by improperly expanding their patent rights, effectively recapture a drug and its use from the public domain (thus keeping less-costly versions of the drug out of the hands of consumers), which Congress could not have meant to do and indeed which Congress likely does not have the power to do. *See Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available."). In short, the Federal Circuit had it right when it held that an off-label use patent cannot serve as the basis for an infringement action under section 271(e)(2).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

EDWARD W. REMUS*
JONATHAN R. SICK
MCANDREWS HELD & MALLOY, LTD.
500 West Madison Street
Suite 3400
Chicago, Illinois 60661
(312) 775-8000

Counsel for Respondent
Bausch & Lomb Incorporated

* *Counsel of Record*

October 24, 2003